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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,712	11/13/2001	Gerald Crabtree	APBI-P08-317	6836
28120	7590	11/19/2003	EXAMINER	
ROPES & GRAY LLP			LAMBERTSON, DAVID A	
ONE INTERNATIONAL PLACE			ART UNIT	
BOSTON, MA 02110-2624			PAPER NUMBER	

1636

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 10/054,712	Applicant(s) CRABTREE ET AL.	
	Examiner David A. Lambertson	Art Unit 1636	

-- The MAILING DATE of this communication app ars on the cov r sh t with th corresp ndenc addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/15/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 12-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 36-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II (claim 11) in the response filed August 15, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-46 are pending in the instant application. Claims 36-46 have been newly added in Applicant's response to the Election/Restriction requirement, and correspond to the elected subject matter. Claims 1-10 and 12-35 are withdrawn from consideration as being drawn to a non-elected invention. Claims 11 and 36-46 are under consideration in the instant Office Action.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows:

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/302,629, filed April 30, 1999, and applications to which Application No. 09/302,629 claims priority. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-

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part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was

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unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Applicant's amendment filed May 9, 2003 is noted. However, this amendment was filed subsequent to the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application, and therefore requires a petition to perfect the claim for priority. No such petition is present in the application, therefore the priority claim cannot be considered valid. Applicant's statement in the amendment that the priority claim was incorrect due to a typographical error on the Transmittal Form, and is therefore not subject to petition, is irrelevant to the instant situation. The first line of the specification on all applications filed after November 29, 2000 must contain the priority reference, which cannot be supplied by either the Oath/Declaration or the Transmittal Form. Furthermore, the Transmittal Form, on which the typographical error was present, clearly states that either a preliminary amendment or an Application Data Sheet (ADS) is required with the claim to priority (see box 18). As such an amendment/ADS was not filed, the priority claim is defective and must be perfected by a petition. Until such perfection is made, the priority date of the instant application is granted only so far as the filing date of the instant application, November 13, 2001.

Information Disclosure Statement

The information disclosure statement filed May 19, 2003 has been considered, and a signed and initialed copy of the form PTO-1449 has been attached to this Office Action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11 and 36-46 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Although the invention indicates a chimeric protein, this does not necessarily indicate the “hand-of-man” as it is well known that chimeric proteins result in nature between heterologous proteins. No matter how unlikely the occurrence as it may relate to the instant invention, the possibility exists that such a chimeric protein is present in a native form. An indication that the chimeric protein is “recombinant” or “isolated” would be remedial to the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 36-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Crabtree et al. (US 5,834,266; see entire document; henceforth Crabtree). It is emphasized that this rejection is presented as the result of the improper priority claim indicated above. Perfection of the priority claim to properly indicate a claim of priority to the instant reference will obviate the rejection.

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Crabtree clearly anticipates the subject matter of the instant claims because the disclosure of the instant specification is identical to the disclosure of the Crabtree specification. Nonetheless, support for the instant rejection can be found throughout the specification of Crabtree, for instance from column 3, line 4, to column 4, line 41. For example, it is here that Crabtree teaches chimeric proteins comprising at least one ligand-binding domain fused to an action domain that is capable of initiating apoptosis in a cell, wherein oligomerization of the chimeric receptor by a ligand initiates apoptosis. The ligand that causes the oligomerization is a non-protein having a molecular weight of less than 5 kDa, is membrane permeable, and binds with a Kd value below about 10^{-6} . In some instances the ligand is an FK506-type ligand. Support for the rejection can be found throughout the specification of Crabtree, therefore the instant claims are anticipated.

Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone

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number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson, Ph.D.
AU 1636



JAMES KETTER
PRIMARY EXAMINER